IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:	
Nordine CHEIKH *et al.*	Art Unit: 1631
Appln. No.: 09/976,054	Examiner: Mary K. ZEMAN
Filed: October 15, 2001	Atty. Docket: 16517.256
Title: **Nucleic Acid Molecules and Other Molecules Associated with the Cytokinin Pathway**	Confirmation No.: 3580

APPELLANT'S BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Mail Stop Appeal Brief - Patents

Sir:

This is an Appeal from the Final Rejection of claims 1, 12 and 14-19 pending in the above-described patent application. A Notice of Appeal was filed on August 4, 2003. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Appellant is unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1 and 12-19 are pending. Claims 1, 12, and 14-19 stand finally rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description support.

Claims 1 and 18-19 stand finally rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make an use the claimed invention.[1] Appellant appeals all of the rejections of each of the claims.

4. Status of Amendments

Applicants have not filed any responses in this case subsequent to the Final Office Action mailed May 5, 2003 ("Final Action").

5. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule that encodes a maize or a soybean adenine phosphoribosyl transferase or fragment thereof, wherein said nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 5. Specification at page 19, line 2 through page 20, line 7. The invention is further directed to a substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5 or complement thereof. *Id.* The invention is further directed to a substantially purified nucleic acid molecule having between 90% and 100% sequence identity with a nucleic acid molecule of SEQ ID NO: 5 or complement thereof. Specification at page 19, line 2 through page 20, line 7; and page 37, line 16 through page 39, line 23. The present invention is further directed to a substantially purified first nucleic acid molecule that encodes a maize or a soybean adenine phosphoribosyl transferase or fragment thereof which specifically hybridizes to a second nucleic acid molecule, the second nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5 or complement thereof. *Id.*

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[1] Claim 13 stands objected to as being dependent on a rejected base claim and is thus not subject to appeal.

6. Issues

The issues in this Appeal are:

(a) whether claims 1, 12, and 14-19 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged insufficiency of written description; and

(b) whether claims 1 and 18-19 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged lack of enablement.

7. Grouping of Claims

Patentability of claims claims 1, 12, and 14-19 is addressed together in Sections 9.A through 9.B below. The separate patentability of claims 1, 18 and 19 is addressed in Section 9.C below. A copy of the claims on appeal is attached hereto as Appendix A.

8. Preliminary Remarks

Applicants thank the Examiner for indicating that claim 13 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants further thank the Examiner for withdrawing the rejections of claim 1 under 35 USC § 102(e), 35 USC § 102(b), and 35 USC § 112, second paragraph. Applicants also thank the Examiner for withdrawal of the objection to the specification for allegedly containing an embedded hyperlink and/or other form of browser-executable code.

9. Argument

A. Summary of Appellant's Position

Applicants have provided an adequate description of the claimed nucleic acids that demonstrates Applicants' possession of the claimed invention. Each genus of claimed nucleic acid molecules, *i.e.*, the nucleic acid molecules comprising the nucleic acid sequences of SEQ ID NO: 5 and its complement, has been described by the recitation of a common structural feature – the nucleotide sequence of SEQ ID NO: 5 and its complement, respectively – which distinguishes molecules in the genus from

molecules not in the claimed genus. Because the specification demonstrates that Applicants have possession of (and have provided an adequate description of) the claimed genus of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

Applicants have asserted that the claimed nucleic acid molecules actually work for the utilities disclosed and described in the specification, and so the enablement rejection must be reversed. Applicants have asserted that one skilled in the art is able to use the claimed nucleic acid molecules for at least two disclosed utilities, namely use to identify the presence or absence of a polymorphism and use as a hybridization probe for expression profiling. *See, e.g.*, specification at page 55, line 5, through page 82, line 16. The law clearly establishes that the enablement requirement is satisfied if at least one mode of making and using the invention is enabled. Because Applicants have asserted that the claimed nucleic acid molecules work for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

B. The Specification Provides An Adequate Written Description of the Claimed Invention

Despite the Examiner's admission that SEQ ID NO: 5 is adequately described by the specification,[2] the adequacy of the written description of claims 1, 12, and 14-19 has been challenged by the Examiner because the subject matter of the claims is allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s)...had possession of the claimed invention." Final Action at page 2. The Examiner contends that "[t]here is no description of an isolated maize or soybean polynucleotide which is a full length polynucleotide comprising an

[2] The Examiner has previously stated that "[c]laims limited to isolated polynucleotides consisting of the SEQ ID NO: 5 would meet the written description provisions of 35 USC § 112, first paragraph." Office Action mailed December 19, 2002, at page 3.

open reading frame which would encode a full length enzyme...[t]herefore, this genus lacks written description." Final Action at pages 2-3. The Examiner further alleges that "[a]pplicant is *not* in possession of any polynucleotide which encodes a maize or soybean APRT enzyme. Therefore, the disclosure is deficient, and the claims lack adequate written description."[3] Final Action at page 3. These assertions do not form a proper basis for a written description rejection of a "comprising" claim. If they did, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Moreover, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules.

(1) The Specification Reflects Applicants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met.

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[3] Applicants note that the Examiner's arguments regarding adequacy of § 112 description fail to specifically address the subject matter of claims 12 and 14-17, which are drawn to a substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5 or complement thereof. Nevertheless, Applicants intend the arguments herein to be fully responsive to alleged rejections of claims 1, 12, and 14-19. Moreover, the Examiner admits that "the claims do not require that the claimed polynucleotide have the recited enzymatic activity." Final Action at page 2. Applicants respectfully and additionally point out that claim 1 is directed to "a substantially purified nucleic acid molecule that encodes a maize or a soybean adenine phosphoribosyl transferase or fragment thereof, wherein said nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 5" (Emphasis added). The claims do not require a polynucleotide comprising an ORF or encoding a full length enzyme and thus Applicants need not describe them.

In re Alton, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of SEQ ID NO: 5 and its complement and therefore, the claimed invention.

Applicants have provided the nucleotide sequences required by the claims, *e.g.*, SEQ ID NO: 5, as well as, for example, vectors comprising these nucleotide sequences, and binary artificial chromosomes (BIBACs) and other systems that may be used to introduce the claimed nucleic acid molecules into a host cell, and have thus established possession of the claimed invention. *See, e.g.,* specification at page 82, line 18 through page 92, line 8. The fact that the claims at issue are intended to cover molecules that include the recited sequences joined with additional sequences, or that hybridize under specific conditions to the recited sequences does not mean that Applicants were any less in possession of the claimed nucleic acid molecules.[4] It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts."[5] *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The present application describes more than just the nucleotide sequence required by the claims (SEQ ID NO: 5), for example, it describes vectors comprising the claimed nucleic acid molecules (specification at page 82, lines 18 through page 92, line 8) and

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[4] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

[5] The Office has asserted that "[a]pplicant cites various pieces of case law which do not refer to polynucleotides, or the particular fact pattern at hand, and are thus non-persuasive." Final Action at page 2. Applicants respectfully submit that it is incorrect as a matter of law to disregard legal precedent simply because the case(s) cited do not concern the biological arts, or more particularly, nucleic acids.

describes how to make the nucleotide sequences and the libraries from which they were originally purified. *See, e.g.,* Example 1 at page 142, *et seq.* Furthermore, the addition of extra nucleotides or detectable labels to the disclosed nucleotide sequences (SEQ ID NO: 5) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[6] for example at page 37, lines 4-8 (describing sequences with labels to facilitate detection), page 50, lines 8-19 (describing fusion nucleic acid molecules), and page 136, line 17 through page 137, line 2 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules).

Moreover, the court determined, in *Enzo Biochecm, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 U.S.P.Q.2d 1609, 1610 (Fed. Cir. 2002), that the written description inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art." *Enzo*, 296 F.3d at 1326-1327, 63 U.S.P.Q.2d at 1615. Moreover, it is well established that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981)).

(2) Applicants Have Described the Claimed Invention

The Examiner asserts that because Applicants have not disclosed "any polynucleotides which encode a maize or soybean APRT enzyme," Applicants have allegedly not adequately disclosed the claimed genera of nucleic acid molecules. Final Action at page 3. The Examiner further asserts that "[o]ne of skill in the art would not be

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[6] It is established patent jurisprudence that Applicant need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

able to determine what fragments, and mutants or alleles would fall within the scope of the claims, or even what the unknown residues should be in the full length sequence." *Id.* The Examiner appears to assert that each nucleic acid molecule within the claimed genera must be described by its complete structure. Final Action at page 3. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

In particular, Applicants have disclosed common structural features, for example the nucleotide sequence of SEQ ID NO: 5. For example, if a particular vector contains the nucleotide sequence of SEQ ID NO: 5, then it is a member of the claimed genus of vectors comprising a nucleic acid sequence of SEQ ID NO: 5.[7] *See* claim 1. Moreover, closely related nucleic acid molecules falling within the scope of the claimed invention are readily identifiable - they either contain the nucleic acid sequences of SEQ ID NO: 5 (or its complement), or hybridize under the claimed conditions to SEQ ID NO: 5 (or its complement), or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

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[7] If a nucleic acid molecule does not contain SEQ ID NO: 5, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 5 or it does not. One skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule such as an mRNA contains a nucleotide sequence having 90% identity to a nucleic acid sequence of SEQ ID NO: 5, then it is a member of that claimed genus of nucleic acid molecules. *See claim 14.*

Thus, claims 1, 12, and 14-19 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

C. The Claimed Nucleic Acids Are Enabled by the Specification

Claims 1, 18 and 19 were erroneously rejected as not being enabled by the specification. The Final Action asserts the claims "contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Final Action pages 3-4. The Examiner apparently maintains that, on the basis of the Wands factors, undue experimentation would be required in order to make and use the claimed invention.

It is well established law that patent applicants are not required to disclose every species enabled by their claims. *See In re Vaeck*, 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991). The enablement requirement is met if the description enables any mode of making and using the invention.

The Examiner cites no support for the proposition that the full scope of the claims would require undue experimentation by one of ordinary skill in the art to make or use the claimed invention for the uses described in Applicants' disclosure. In particular, Applicants have previously stated that the claimed nucleic acid molecules are useful as markers and probes (*see, e.g.,* specification at page 37, line 4 through page 40, line 10; specification at page 71, lines 3-13); to identify and obtain nucleic acid homologues (*see, e.g.,* specification at page 55, line 6 through page 57, line 2); to identify the presence or absence of a polymorphism (*see, e.g.,* specification at page 58, line 7 through page 66, line 2); to identify the concentration, presence or expression pattern of mRNA in a sample (*see, e.g.,* specification at page 71, line 14 through page 78, line 3); use to transform plants and other organisms (*see, e.g.,* specification at page 82, line 17 thorough

page 101, line 11); and use to overexpress or suppress a desired protein (*see, e.g.,* specification at page 101, line 12 through page 103, line 22).

In addition, the claimed nucleic acid molecules are particularly useful, for example, to isolate a promoter active in the cytokinin pathway of a maize or soybean plant. *See, e.g.,* specification at page 57, line 3 through page 58, line 6; Example 1; Table A; Example 3; and original claims. Furthermore, because each of the claimed nucleic acid molecules has been asserted in the specification to encode a maize adenine phosphoribosyl transferase or fragment thereof, use of the claimed nucleic acid molecules have particular relevance, for example, to the identification of polymorphisms, promoters, and patterns of expression of this enzyme. The Examiner has cited no direct support for the proposition that the claimed nucleic acid molecules are not enabled for these uses.[8]

In view of the Examiner's admission that SEQ ID NO: 5 is enabled, and the well established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques" (*see, for example, Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000)), which would include the use of the claimed sequence with other nucleic acid sequences, Applicants submit the Examiner has not met the required burden. Applicants further assert that the use of the transitional phrase "comprising", which leaves the claims "open

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[8] The Examiner has not provided direct evidence refuting the use of the **specific** sequence of SEQ ID NO: 5 in the manner described in the specification. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement). Applicants acknowledge the Examiner's citation of Moffatt; however, Applicants maintain that Moffatt has been improperly characterized by the Office. *See, e.g.*, Applicants' Response to the Office Action mailed December 19, 2002 (stating "Although the Examiner contends the U.S. Patent No. 5,770,718 supports the assertion that the claimed invention is not enabled because 'differing known genes are *lacking in sequence similarity,* and that previous hybridization experiments to identify APRT encoding sequences had been unsuccessful' Office Action at page 7) (emphasis in original), what the patent actually says is that attempts to isolate the apt cDNA in Arabidopsis via cross hybridization with previously isolated apt sequences (*e.g.*, sequences isolated for mouse, hamster and human) were unsuccessful. See Col. 2 , ii. 50-62, col. 3, l. 52-col. 4, l.4.")

for the inclusion of unspecified ingredients even in major amounts" (*Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986)) is well-established in patent jurisprudence.

The Final Action attempts to abrogate the Examiner's burden to present evidence that the claims are not enabled by providing generic arguments concerning the alleged unpredictability of nucleic acid hybridization and cloning experiments. Final Action at pages 4-5. In response, Applicants submit that an analysis of the criteria presented by *In re Wands* supports Applicants' position that no undue experimentation would be required to make and use the claimed invention. *See In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1998). Applicants note that the *Wands* factors were previously addressed in Applicants' Response dated March 19, 2003, and are supplemented herein below.

The first *Wands* criterion is the quantity of experimentation necessary. The "make-and-test" quantum of experimentation is reduced by the extensive knowledge, *e.g.*, of conservative nucleotide substitutions and of hybridization parameters, to which a person of ordinary skill in the art has access. Performing routine and well-known steps, such as sequence alignment protocols, molecular weight determination, and antibody hybridization assays, cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 218-219 (C.C.P.A. 1976). Thus, the addition of nucleotides to the recited sequence, the identification of nucleic acid molecules that hybridize to the claimed nucleic acid molecules, and the conception of variations in the claimed nucleic acid molecule that encode a protein having one or more conservative amino acid changes is rendered predictable to one of ordinary skill in the art.

The second and third *Wands* criteria relate to the amount of direction or guidance given, and the presence or absence of working examples. Again, the specification provides evidence of sequence identity, discusses the use of the claimed SEQ ID NO to isolate additional sequences within a genome, and describes how to isolate and generate libraries from the nucleic acid molecules. *See, e.g.,* Table A at page 208, page 55 line 5 *et seq.*, and Examples 1-3, page 142 *et seq.* Based on such disclosure, one of ordinary skill in the art would be enabled to make and use the invention commensurate in scope with the claims.

The fourth, fifth, and sixth *Wands* criteria focus on the nature of the invention, the state of the art, and the relative skill in the art. The present invention relates to nucleic acid molecules comprising nucleic acid sequences, and the specification further describes amino acid sequences derived therefrom, and constructs and methods related thereto. *See, e.g.*, specification at page 42, line 3 through page 44, line 21, and at page 48, line 20 through page 57, line 2 (describing polypeptide molecules and homologues); and page 82, line 17 through page 101, line 11 (describing use of the claimed nucleic acid molecules in methods of transforming plants). Practitioners in this art are guided by considerable knowledge and resources on the conditions and approaches that can be utilized to identify, confirm, and introduce into other hosts, nucleic acid and amino acid sequences.

The seventh criterion considers the predictability of the art. Applicants respectfully assert, as discussed *supra*, that the specification discloses, for example, sufficient guidance to render the results of substitutions, additions, and deletions within the claimed SEQ ID NOs predictable. *See, e.g.,* specification at page 42, line 3 through page 44, line 21; page 48, line 20 through page 57, line 2; and the sequence listing.

The eighth criterion focuses on the breadth of the claims. Enablement is satisfied when the disclosure "adequately guide[s] the art worker to determine, without undue

experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility". *See In re Vaeck,* 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). In the present case, one of skill in the art is specifically guided by the disclosure to look to, *e.g.*, sequence identity data in making that determination.

Finally, the Examiner alleges that "Applicant has not provided evidence wherein the inventors or one of skill in the art has obtained a sequence meeting the limitation of claim 1 wherein only the guidance in the specification was used. Such later-produced evidence could be persuasive, as long as it clearly follows the teachings of the specification and does not use techniques, information or procedures which go beyond the teaching in the specification." Final Action at pages 4-5. The Examiner appears to assert that, in order for the claims to be enabled, one of skill in the art must be able to make and use the invention using *only* the guidance in the specification. Such an assertion is incorrect as a matter of law. Applicants need only show that one skilled in the art would be able to make and use the claimed invention using the application as a guide. *In re Brandstadter*, 484 F.2d 1395, 1406-07, 179 U.S.P.Q. 286, 294 (C.C.P.A. 1973). In order to be enabling, the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well known to those skilled and already available to the public. *See, e.g.,* M.P.E.P. § 2164.05(a), page 2100-185, *citing In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q. 2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies*, Inc., 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1463, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984).

The Examiner has presented no evidence supporting the allegation that one of ordinary skill in the art would not be able to make or use the claimed nucleic acid molecules in light of Applicants' disclosure. Furthermore, the analysis of the Wands

factors, discussed *supra*, conclusively establishes that one of ordinary skill in the art would be able to make and use the claimed invention based on the disclosure in the specification. Accordingly, for at least these reasons, the enablement rejection under 35 USC § 112, first paragraph, is improper and must be reversed.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

Date: October 6, 2003

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